

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Kenneth Iain Cumming

Application No.: 09/510,560

Filed: February 22, 2000

For: **SOLID ORAL DOSAGE FORM CONTAINING AN ENHANCER**

Confirmation No.: 3011

Group Art Unit: 1639

Examiner: Jeffrey S. Lundgren

Date: June 13, 2008

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**RESPONSE TO ELECTION REQUIREMENT**

Sir:

This response is submitted in reply to the Official Action dated June 4, 2008 ("the Action"). In the Action, the Examiner required an election from the following species:

- Species A. *whether or not the composition has an enteric coating* – Applicants are required to elect whether or not their dosage form has an enteric coating, and if so, the chemical composition of the coating (e.g., claim 259);
- Species B. *the number and chemical composition of absorption enhancers* – Applicants are required to elect how many enhancers are in the formulation and if there are any additional enhancers to sodium caprate, which enhancers are being elected;
- Species C. *a single combination of excipients* – Applicant are required to elect a single combination of excipients (e.g., rate-controlling polymeric materials, diluents, lubricants, etc.), and specify the particular excipients by appropriate chemical names (e.g., microcrystalline cellulose for the inert filler as in claims 293);
- Species D. *the type of formulation release* – Applicants are required to elect a single formulation release, such as, instant-release (e.g., claim 283), sustained release (e.g., claim 280);
- Species E *the form of the formulation* – Applicants are required to elect a single physical form of the pharmaceutical formulation, e.g., a multiparticulate tablet as in claim 286, or an enteric coated capsule as in claim 261.

Applicants hereby elect, **with traverse**, the following species.

For Species A, Applicants elect a composition having an enteric coating, which comprises polymethacrylate. Claims 258-345 read on the elected species.

For Species B, Applicants elect a composition having a single absorption enhancer which is sodium caprate. Claims 258-289, 291-332, and 334-345 read on the elected species.

For Species C, Applicants elect a single combination of excipients consisting of an inert filler, which is sorbitol; a disintegrant, which is crospovidone; and a lubricant, which is stearic acid. Claims 258-280, 283-290, 292, 295-300, 302, 303, 306, 309-314, and 316-345 read on the elected species.

For Species D, Applicants elect a composition which is an instant release formulation. Claims 258-279, 283-290, 292-303, and 306-345 read on the elected species.

For Species E, Applicants elect a composition which is a tablet. Claims 258-260 and 262-345 read on the elected species.

Applicants traverse the required election of species for Species A, C, D, and E as improper. Each of the categories in A (enteric coating vs. no enteric coating), C (choice of excipients), D (instant release vs. sustained release), and E (tablet vs. capsule) relates to aspects of a composition for pharmaceutical use that are often varied by those of skill in the pharmaceutical arts. Many of the choices in these categories are well known to those of skill in the art in both structure and function and do not represent independent and distinct species (see M.P.E.P. 806.04(b)). Thus, a requirement for an election of species is improper.

Applicant respectfully submits that this application is now in condition for substantive examination, which action is requested.

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If any extension of time for the accompanying response or submission is required, Applicant requests that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to our Deposit Account No. 50-0220.

Respectfully submitted,



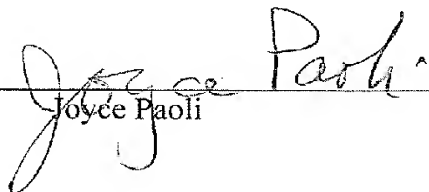
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**CERTIFICATION OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4) to the U.S. Patent and Trademark Office on June 13, 2008.

Signature: \_\_\_\_\_

  
Joyce Paoli